EXHIBIT A

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Paper 36
Date: March 5, 2025

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NOVARTIS PHARMACEUTICALS CORPORATION,
Petitioner,

v.

REGENTS OF THE UNIVERSITY OF MICHIGAN AND UNIVERSITY OF SOUTH FLORIDA,
Patent Owner.

IPR2023-01346
Patent 10,633,344 B2

Before JEFFREY N. FREDMAN, MICHAEL J. FITZPATRICK, and SHERIDAN K. SNEDDEN, *Administrative Patent Judges.*

SNEDDEN, *Administrative Patent Judge*.

JUDGEMENT

Final Written Decision
Determining All Challenged Claims Unpatentable
35 U.S.C. § 318(a)

I. INTRODUCTION

We issue this Final Written Decision pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73 in an *inter partes* review involving Novartis Pharmaceuticals Corporation ("Petitioner") and University of South Florida and Regents of The University of Michigan (collectively, "Patent Owner"). We have jurisdiction under 35 U.S.C. § 6. Based on the record before us, we conclude that Petitioner has demonstrated, by a preponderance of the evidence, that claims 10, 11, and 18 of U.S. Patent No. 10,633,344 ("the '344 patent," Ex. 1001) are unpatentable.

A. Background and Summary

Petitioner filed its Petition requesting *inter partes* review of claims 10, 11, and 18 of the '344 patent. Paper 4 ("Pet."). Patent Owner did not file a Preliminary Response. Based on the record before us, we instituted *inter partes* review of all claims and all grounds asserted in the Petition. Paper 8 ("Institution Decision" or "Dec.").

Subsequent to our Institution Decision, Patent Owner filed a Response to the Petition (Paper 19, "PO Resp."), Petitioner filed a Reply to Patent Owner's Response (Paper 22, "Reply"), and Patent Owner filed a Sur-Reply (Paper 25, "Sur-Reply").

On January 8, 2025, the parties presented arguments at an oral hearing. The transcript of the hearing has been entered into the record. Paper 35 ("Tr.").

B. The '344 patent

The '344 patent discloses "a method for identifying complementary chemical functionalities to form a desired supramolecular synthon." Ex. 1001, Abst. In particular, "[t]he subject invention relates to the

application of the concepts of crystal engineering towards the design of new pharmaceutical solid phases . . . using cocrystal formers that are complementary in the sense of supramolecular chemistry, i.e., they form supramolecular synthons with pharmaceutical molecules or ions." Ex. 1001, 3:29–34, *see also id*. at 4:10-12 (describing "identifying co-crystal formers having chemical functionalities that are complementary with the API.". The '344 patent discloses that "[t]he ability of crystalline self-assemblies to be built from a bottom-up approach could provide an exceptional control of the design of new phases at a molecular level." *Id.* at 2:1–4. Such "novel crystalline assemblies can afford improved drug solubility, dissolution rate, stability and bioavailability." *Id.* at 3:26–28.

The '344 patent claims are directed to pharmaceutical compositions "comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of co-crystal." *Id.* at 25:18–20. The co-crystal is a "supramolecular synthon," which "refers to the sum of the components of a multi-component noncovalent interaction." *Id.* at 9:66–10:1. "[T]he term 'multiple-component phase' refers to any solid material (phase) that is sustained by intermolecular interactions between at least two independent molecular entities, in any stoichiometric ratio, wherein at least one of the independent molecular entities is a pharmaceutical entity." *Id.* at 9:10–15. Thus, the supramolecular synthon is "formed from stoichiometric amounts of at least one active pharmaceutical ingredient (API) and at least one co-former." *Id.* at 25:21–23.

The API must have a "first chemical functionality that permits formation of API homosynthons through non-covalent hydrogen bonding." *Id.* at 25:24–26. Importantly, the API's first chemical functionality is

limited to one of three functional groups: (i) a carboxamide, (ii) a carbonyl, or (iii) an amine. *Id.* at 25:38–39.

The '344 patent describes co-formers as "solvent molecules, other drug molecules, GRAS compounds, or approved food additives." *Id.* at 3:35–37. The co-former must have "a second chemical functionality complementary to the first chemical functionality via non-covalent hydrogen bonding." *Id.* at 25:28–30.

The '344 patent discloses methods "to identify complementary chemical functionalities and produce multiple-component phase compositions for a variety of pharmaceuticals." Ex. 1001, 9:4–6. Figure 24 of the '344 patent, reproduced below, "shows an exemplified scheme for preparing multiple-component phase compositions of the subject invention." *Id.* at 7:13–15.

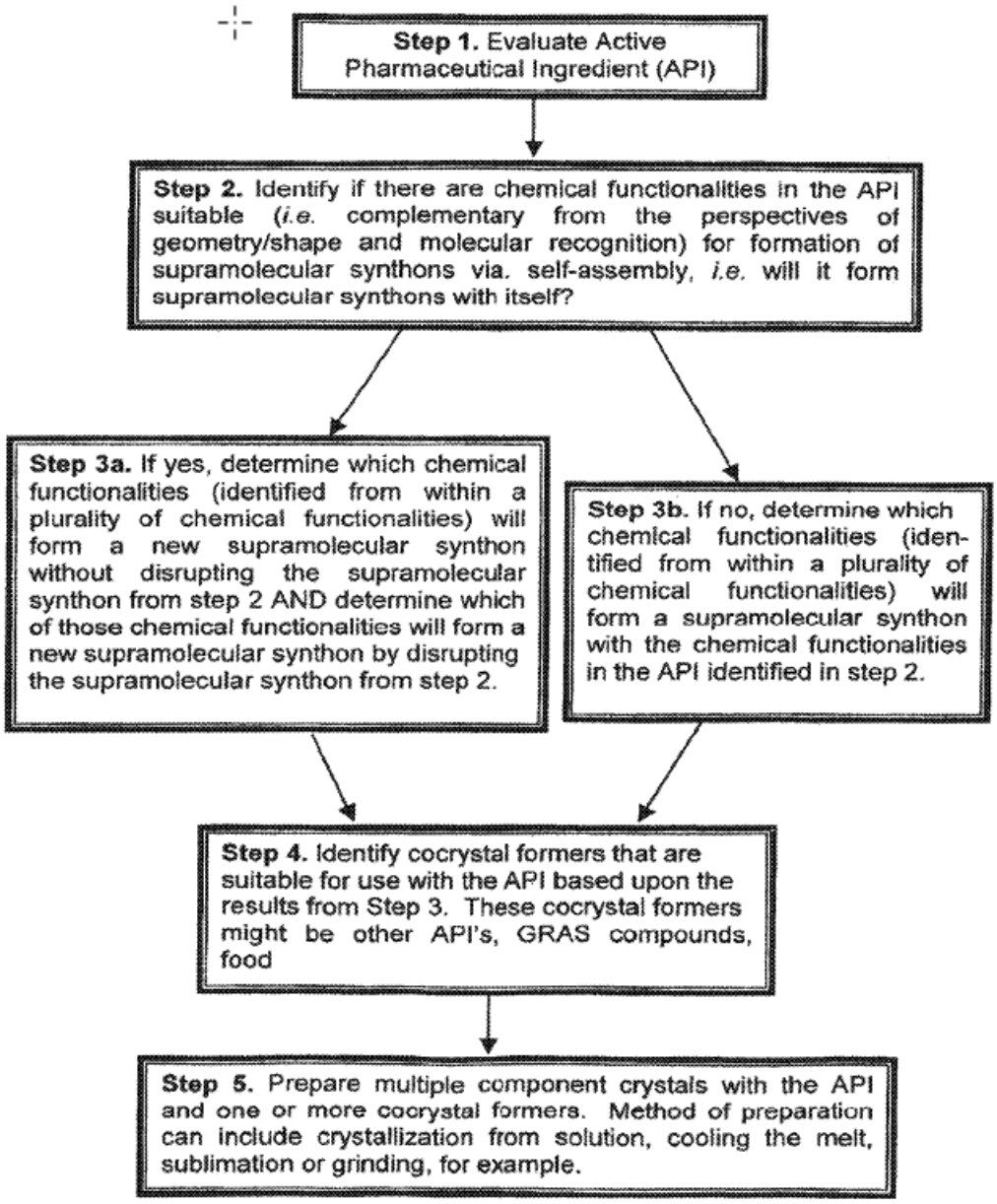

FIG. 24

According to Patent Owner, the flow chart provided in Figure 24 is there to "assist in the selection of an API and conformer based on their chemical functionalities." PO Resp. 16.

C. The Challenged Claims

Petitioner challenges claims 10, 11 and 18 of the '344 patent. In mapping the prior art to claim 10, the Petition breaks the claim into seven

portions, labeled [10A] through [1G], and organizes its arguments accordingly. *See*, *e.g.*, Pet. 35–43. Claims 10, 11 and 18 are reproduced below with the Petitioner's bracketed labels:

> 10. [10a] A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of [10b] a co-crystal comprising supramolecular synthons, each supramolecular synthon formed from stoichiometric amounts of at least one active pharmaceutical ingredient (API) and at least one co-former,
>
> [10c] wherein the API has a first chemical functionality that permits formation of API homosynthons through non-covalent hydrogen bonding when the API is in its pure form,
>
> [10d] wherein the co-former has a second chemical functionality complementary to the first chemical functionality via non-covalent hydrogen bonding,
>
> [10e] wherein said co-former is a solid at room temperature and atmospheric pressure when the co-former is in its pure form,
>
> [10f] wherein supramolecular synthons are formed via non-covalent hydrogen bonding between the first chemical functionality of the API and the second chemical functionality of the co-former, and
>
> [10g] wherein the first chemical functionality is (i) a carboxamide, (ii) a carbonyl, or (iii) an amine.
>
> 11. The pharmaceutical composition of claim 10, wherein the supramolecular synthon comprises a heterosynthon dimer formed by non-covalent hydrogen bonding of the API to the co-former.
>
> 18. The pharmaceutical composition of claim 10, wherein the first chemical functionality is a carboxamide.

Ex. 1001, 25:18–39, 25:40–43, 26:22–23.

D. Evidence

Petitioner relies upon information that includes the following.

> Ex. 1004, Hickey et al., "Performance Comparison of a Co-Crystal of Carbamazepine with Marketed Product," 67 EUR. J. PHARM. & BIOPHARM. 112–119 (2007) ("Hickey").
>
> Ex. 1005, Almarsson, US Pat. No. 7,927,613 B2, published April, 19, 2011 ("Almarsson").
>
> Ex. 1006, Martindale, The Complete Drug Reference (37th ed. 2011) ("Martindale").

Petitioner also relies on the Declaration of Robin D. Rogers, Ph.D. (Ex. 1002) and Leah Appel, Ph.D. (Ex. 1003) to support its contentions.

Patent Owner relies on the Declaration of Michael D. Ward, Ph.D. (Ex. 2014) to support its contentions.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 10, 11 and 18 would have been unpatentable on the following grounds:

Ground	Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1	10, 11, 18	102(b)	Hickey
2	10, 11, 18	102(b)/103(a)	Almarsson
3	10, 11, 18	103(a)	Almarsson, Hickey, Martindale

F. Level of Ordinary Skill in the Art

Petitioner asserts that a person of ordinary skill in the art ("POSA" or "POSITA") at the time of the invention

> would have had a Ph.D. in chemistry or a related field with at least two years of experience in solid state chemistry, including experience preparing multiple-component crystalline solids and evaluating their single crystal structures. Alternatively, a POSA

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. § 103, effective March 16, 2013. Because the application leading to the '344 patent claims priority to an application filed before March 16, 2013, we apply the pre-AIA version of 35 U.S.C. § 103.

> would have had a Ph.D. in chemistry, pharmacy, or a related field with at least two years of experience in formulation of pharmaceutical compositions, and the POSA would consult with others having ordinary experience in other disciplines, such as solid-state chemistry, including experience preparing multiple-component crystalline solids and evaluating their single crystal structures.

Pet. 7–8. "Patent Owners do not contest the level of ordinary skill in the art set forth in the Petition." PO Resp. 11.

Because Petitioner's unopposed definition is consistent with the '344 patent and the prior art of record, we adopt that definition. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1354–55 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579–80 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978).

G. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2019). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes constructions for the terms "active pharmaceutical ingredient (API)", "API homosynthons", "carbonyl", "carboxamide", "co-former", "heterosynthon dimer", and "supramolecular synthon." Pet. 9–10. Petitioner represents that the proposed constructions have been agreed to between the parties in parallel litigation, or agreed upon such that "the disputed portions are not relevant to the issues raised in this Petition." *Id.* at 8; *see also* PO Resp. 12 ("Patent Owners agree with the application of the

parties' constructions from the district court litigation identified in the Petition."). We have reviewed each of these constructions and adopt Petitioner's proposed constructions. Petitioner's constructions align with the plain words of the claims, are consistent with the prosecution history of the '344 patent, and find support in the uncontroverted testimony of Dr. Rogers. Ex. 1002 ¶¶ 55–64; Ex. 1016, 256–58, 261–63.

In addition, according to Petitioner, "[t]he parties agree that co-former is used synonymously with co-crystal former and that a co-former is a component of a co-crystal." *Id.* at 9. Petitioner construes the term "co-crystal" to mean "[a] multiple-component, single crystalline phase, having a fixed stoichiometry of its component compounds." *Id.* at 10. Petitioner states that the proposed construction of the term "co-crystal" is "currently disputed in parallel litigation; however, because the claims are unpatentable under Patent Owners' constructions, Petitioner adopts those constructions solely for the purpose of this Petition." *Id.* at 8. We also adopt Petitioner's proposed construction of "co-crystal" for the purposes of this Decision.

We determiner no other terms require express construction. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (per curiam) (claim terms need to be construed "only to the extent necessary to resolve the controversy") (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)). To the extent further discussion of the meaning of any claim term is necessary to our decision, we provide that discussion below in our analysis of the asserted grounds of unpatentability.

II. EFFECTIVE FILING DATE OF THE CHALLENGED CLAIMS

The '344 patent issued from U.S. application Ser. No. 14/179,862

("the '862 application"), filed on February 13, 2014, which claims priority as a continuation to U.S. application Ser. No. 10/378,956 ("the '956 application"), filed Mar. 3, 2003, and to U.S. Provisional Application Ser. No. 60/360,768, filed Mar. 1, 2002 (collectively, "the Priority Applications"). Ex. 1001, at [21], [22], [60], [63].

Petitioner contends that "Patent Owner[] will be unable to meet their burden of production of showing written description and enablement support for the challenged claims as of those 2002/2003 filing dates [of the Priority Applications], as required by 35 U.S.C. §§ 112 and 120 (pre-AIA)." Pet. 11. "As a result, the earliest possible priority date for the challenged claims is the February 13, 2014 filing date of the '862 application." *Id*.

Patent Owner contends that "[t]he asserted references are not prior art to the '344 Patent because at least the '956 Application provides written description support for and enables the Challenged Claims, which are therefore entitled to a priority date no later than 2003 and predates all of the asserted prior art." PO Resp. 16.

For the reasons discussed below, we find that the specification of the '956 application[2] fails to provide adequate written description support for the challenged claims. Accordingly, we determine that the effective filing

[2] In the parties' briefs and in the discussion that follows, references are made to the '344 patent, the '956 application, and to the specification generally. Because the '344 patent claims the benefit of priority to the '956 application as a continuation, the two documents share a common specification, apart from their claims as filed. Thus, any general reference to "the specification" applies equally to the '344 patent specification and the specification of the '956 application as the two documents contain a substantively identical disclosure.

date for claims 10, 11, and 18 is February 13, 2014, the filing date the '344 patent.

A. Principles of Law

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). The burden of persuasion never shifts to Patent Owner. *Dynamic Drinkware, LLC v. Nat'l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015). However, the burden of production is on the Patent Owner to show that the claim is entitled to a filing date prior to the date of the alleged prior art. *See Tech. Licensing Corp. v. Videotek, Inc.*, 545 F.3d 1316, 1327 (Fed. Cir. 2008). That is, Patent Owner must come forward with evidence and argument showing that the challenged claim is supported by the written description of the priority applications.

Pursuant to 35 U.S.C. § 120, a patent application is entitled to assert priority to the filing date of a prior application only "for an invention disclosed [in the prior application] in the manner provided by" 35 U.S.C. § 112. The test for sufficiency of a written description under 35 U.S.C. § 112, ¶ 1, is whether the earlier application's disclosure "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). That "test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art." *Ariad*, 598 F.3d at 1351. "[T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the

complexity and predictability of the relevant technology." *Id.* (citing *Capon v. Eshhar*, 418 F.3d 1349, 1357–58 (Fed.Cir.2005)).

For a genus claim, written description support may be found where the specification identifies "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Id.* at 1350 (citing *Regents of the Univ. of California v. Eli Lilly & Co*., 119 F.3d 1559, 1568 (Fed. Cir. 1997)). That "requires a precise definition, such as by structure, formula, chemical name, physical properties, or other properties, of species falling within the genus sufficient to distinguish the genus from other materials." *Ariad*, 598 F.3d at 1350 (citations omitted). "Otherwise, one has only a research plan, leaving it to others to explore the unknown contours of the claimed genus." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc*., 759 F.3d 1285, 1300 (Fed. Cir. 2014).

Adequate written description may be present in "functional" terminology "when the art has established a correlation between structure and function." *Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1378 (Fed. Cir. 2017) (citing *Ariad*, 598 F.3d at 1350).

B. Petitioner's Contentions

According to Petitioner, "[t]he challenged claims are extremely broad [because] [t]hey are not limited to a specific co-crystal, or even a small group of co-crystals." Pet. 12. In particular, Petitioner contends that the recited API and co-former are each selected from a large genus of potential APIs and co-formers, respectively. Pet. 12 ("the API may be selected from a

large genus of potential APIs and the co-former from a large genus of potential co-formers") (citing Ex. 1002 ¶¶ 69–74). Petitioner asserts that,

> beyond specifying that the API must have a carboxamide, carbonyl, or amine first chemical functionality, and the supramolecular synthons must comprise certain hydrogen bonds, the challenged claims do not limit the structure of the co-crystal or its API and co-former components. [Ex. 1002] ¶¶ 69–74. Essentially, limitless structural variations are permitted.

Id.; *see also* Ex. 1002 ¶¶ 72–74 (Dr. Rogers testifying that "the API and co-former can be present in any stoichiometric ratio, and additional molecules like solvent molecules can also be part of the co-crystal (*see*, *e.g.*, dependent claim 16 which discusses such solvates of co-crystals), making the number of possible co-crystals covered by the challenged claims almost infinite.").

Petitioner further asserts that there are no structural features common to all embodiments of the challenged claims "because the challenged claims do not limit the structure of the API (beyond specifying the first chemical functionality) or the co-former of the claimed co-crystals, let alone their structures when combined into a co-crystal." Pet. 13 (citing Ex. 1002 ¶¶ 69, 75). To that point, Dr. Rogers notes that the claims recite

> function, not structure, *i.e.*, the co-crystal is *formed from* the API and co-former, the API and co-former must *form* supramolecular synthons between the first chemical functionality of the API (carboxamide, carbonyl, or amine) and the unspecified complementary second chemical functionality of the co-former, and the API must *permit formation* of API homosynthons through noncovalent hydrogen bonding when the API is in its pure form.

Ex. 1002 ¶ 69.

Petitioner asserts also that "[t]he Priority Applications fail to provide a representative number of species to support the breadth of the challenged claims." *Id.* (citing Ex. 1002 ¶¶ 69, 75–82). Petitioner argues that "there are

only ten Examples where the API has a carboxamide or amine and the co-former is solid, as required by the challenged claims." Pet. 13 (citing Ex. 1002 ¶¶ 76–77). Specifically, Example 2 discloses a co-crystal with "hydrogen bonding of adjacent phenytoin molecules between the carbonyl and the amine closest to the tetrahedral carbon." Ex. 1001, 12:44–46. Example 7 discloses a co-crystal with "hydrogen bonded carboxamide homodimers that crystallize in the space group C2/c." *Id.* at 16:24–26. Examples 8, 9, and 14 disclose co-crystals with "hydrogen bonded carboxamide homodimers." *Id.* at 17:13–14, 18:1–2, 21:3–4. Example 10 discloses a molecule where "[e]ach hydrogen on the CBZ 1° amine is hydrogen bonded to a carbonyl group of a different 2,6-pyridinedicarboxylic acid moiety." *Id.* at 18:53–55. Example 12 discloses a co-crystal with "hydrogen bonded carboxamide-carboxylic heterodimers." *Id.* at 20:1–2. Example 15 discloses a co-crystal with "hydrogen bonded carboxamide-carboxylic heterodimers between the carbamazepine moieties and the butyric acid moieties." *Id.* at 21:36–38. Example 16 discloses a co-crystal with "hydrogen bonded carboxamide homosynthon." *Id.* at 22:1–2. Example 17 discloses a co-crystal with a "hydrogen bonded carboxamide homodimers between two carbamazepine moieties and carboxylic acids homodimers between two formamide moieties." *Id.* at 22:38–41. Thus, according to Petitioner, "[t]hese ten Examples (involving only three different APIs with a carboxamide or amine and no examples of an API with a carbonyl first chemical functionality) are not representative of all APIs and co-formers that provide co-crystals encompassed by the challenged claims." Pet. 15–16 (citing Ex. 1002 ¶¶ 76–78). Petitioner asserts that "the Priority Applications do not provide any correlation between the structure of any

given co-former or its 'second chemical functionality' and the function required by the claims." *Id.* at 16 (citing Ex. 1002 ¶¶ 77–78, 80–82).

Finally, Petitioner contends that "no Example in the Priority Applications involves a co-crystal where the API has a first chemical functionality that is a carbonyl." Pet. 13 (citing Ex. 1002 ¶ 76).

C. Patent Owner's Response

Patent Owner alleges that "a POSITA would recognize that the claimed co-crystals have similar structures based on the hydrogen bonding between the active pharmaceutical ingredients and their co-formers." PO Resp. 2. Patent Owner contends that a person of ordinary skill in the art would have understood the well-known principles of hydrogen bonding, including the work of Dr. Etter who published a set of rules regarding the general principles of hydrogen bonding and the application of those general principles to co-crystals. *Id.* at 7 (citing Ex. 2014 ¶¶ 38–43; Ex. 2005 (Etter Rules) 124–125). Patent Owner contends that "[t]he well-known principles of hydrogen bonding, including those set forth by Dr. Etter . . . , would allow a POSITA to predict whether a co-crystal of an API satisfying [the challenged claims] would form, regardless of whether a particular polymorph of a co-crystal forms or not." *Id.* at 17.

Patent Owner further contends that co-crystals were well-known in the art. *Id.* at 10 (citing Ex. 2014 ¶ 31 ("knowledge of pharmaceutical co-crystals was emerging"). Patent Owner contends that "a POSITA would have viewed co-crystallization of an API as [a] purification step in the formulation of a pharmaceutical composition." *Id.* at 8 (citing Ex. 2014 ¶ 44). Patent Owner further contends that "[a] POSITA would also have understood the basic principles of formulating a pharmaceutical

composition, including testing the various properties of a formulation such as solubility." *Id.* Thus, according to Patent Owner, a person of ordinary skill in the art would have understood "the types of available solvents and co-formers appropriate for pharmaceutical use, and the solvent(s) and co-former(s) in which the API and co-former prospects would or would not be soluble." PO Resp. 8–9 (citing Ex. 2014 ¶ 44).

Using that knowledge, a POSITA would look to "FDA-approved solvents, co-formers, and/or GRAS compounds" in the crystallization step. *Id.* at 19 (citing Ex. 2014 ¶¶ 44-45). "Then, a POSITA would then have been able to use high-throughput crystallization to quickly and easily identify for the appropriate conditions under which a co-crystal would form by, for example, testing numerous solvents at once." *Id.* (citing Ex. 2014 ¶¶ 47–49); *see also id.* at 10–11 (A POSITA would then have been able to apply the well-known methods of high-throughput screening "to identify and optimize the conditions for co-crystallization."). Thus, "a POSITA would have been able to identify, for example, different solvents to see which could be used to form a co-crystal." *Id.* at 10–11 (citing Ex. 2014 ¶¶ 48–49).

D. Petitioner's Reply

Petitioner first contends that Patent Owner "did not contest that the '956 application lacks disclosure of a representative number of species" and therefore waived any argument under this test for written description. Reply 12. Regarding the common structural features test, Petitioner contends that Patent Owner's argument focuses on the co-crystals themselves and does not address which of the large genus of co-formers will form co-crystals with any given API in the large genus of APIs. Reply 13 (citing PO Resp. 2). Petitioner contends that,

> apart from disclosing a handful of co-crystals actually made, the examples do not enable[3] the POSA to visualize or recognize which other combinations of APIs and co-formers will in fact form the claimed co-crystals. Ex. 1072, ¶¶79-84. The examples fail to account for the diversity and breadth of claims, encompassing myriad combinations of no less than 50 APIs, thousands of co-formers, and 27 solvents.

Id. at 14. Petitioner notes also that none of the examples in the Priority Applications exemplify co-crystals where a "carbonyl" or "amine" was used as a "first chemical functionality." *Id.* (citing Ex. 1072 ¶¶ 79, 83); *see also* Ex. 1072 ¶ 15 ("Dr. Ward's own Appendix C does not identify any examples in the '344 patent or '956 application wherein the first chemical functionality of the API is a carbonyl or amine—two of the three first chemical functionality options for claims 10 and 11."); Ex. 2014, Appendix C. Thus, according to Petitioner, Patent Owner fails to identify any "structural features common to APIs and co-formers that enable a POSA to reasonably predict which ones would form a claimed synthon or co-crystal." *Id.* at 13–14 (Ex. 1002 ¶ 75; Ex. 1072 ¶ 78). "In view of the large number of possible APIs and co-formers, and the fact that co-crystal formation was (and still is) unpredictable . . . , Patent Owners have disclosed nothing more than a research plan." *Id.* at 14.

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[3] Patent Owner takes issue with Petitioner's use of the term "enable" here, suggesting that Petitioner's arguments conflate the written description and enablement requirements under 35 U.S.C. § 112. Sur-Reply 10–11. We are not persuaded that Petitioner's use of the term "enable" in any way undermines its argument, especially in view of Petitioner's use of the phrase "visualize or recognize" in the same sentence, language that is used in *Ariad* to articulate the written description requirement. *Ariad*, 598 F.3d at 1350. Rather, we find Petitioner's use of "enable" in this context to be synonymous with "allow" or "permit" and that the basis of Petitioner's argument concerns the written description standard articulated in *Ariad*.

Petitioner further contends that basic knowledge of hydrogen bonding principles or high-throughput screening methodology does not establish a structure-function correlation nor does it overcome the lack of predictability in co-crystal synthon formation. *Id.* at 15–17 (Ex. 1072 ¶¶ 43–45, 85–92).

E. Patent Owner's Sur-reply

Patent Owner contends that "Petitioner ignores the high level of education and training of a POSITA when analyzing whether the inventors were in possession of the claimed invention." Sur-Reply 7–8. In particular, Patent Owner contends that "Petitioner ignores a POSITA's extensive knowledge of hydrogen bonding and pharmaceutical formulation" in its assessment alleging lack of written description support. *Id.* at 8. In particular, Patent Owner contends that the specification need not provide details of Etter's rules concerning hydrogen bonding, pharmaceutical preformulations, and high-throughput screening methodology as all of this knowledge was well known in the art. More specifically, Patent Owner contends that the Etter rules were well known in the art and "that Etter's rules do, in fact, work." Sur-Reply 3 (citing (Ex. 1081, 1; Ex. 1082, 7). "Thus, contrary to Petitioner's assertions otherwise, a POSITA would be able to use Etter's rules to predict and expect the formation of the claimed co-crystals." *Id.* at 5. Patent Owner concludes that "[t]he '344 patent need not, therefore, delineate each and every step of the 'preformulation' work that the Petitioner identifies is missing – a POSITA would bring that education, training, and knowledge to the table." *Id.*

Patent Owner further contends that

> a POSITA in 2003 would have an understanding of hydrogen bonding and, therefore, understand which APIs and co-formers were likely to form a co-crystal. For example, the POSITA would

> have: (1) an understanding of the likelihood of certain functional groups forming supramolecular synthons; (2) an understanding of a ranking of certain functional groups to form supramolecular synthons in the event multiple hydrogen bonding groups were present; and (3) sufficient working knowledge of whether hydrogen bonds between the API and some collection of co-formers were likely and, in the event of multiple potential synthons, the POSITA would have had a working knowledge of which ones would be preferred, even though other factors could impact synthon formation.

Id. at 9–10 (citing Ex. 2014 ¶¶ 54–55). Here, Dr. Ward testifies that, by following Etter's rules, "a POSA in 2002/2003 would also have a good understanding of the likelihood of certain functional groups forming supramolecular synthons, and indeed would understand the ranking of the likelihood of their formation in the event multiple hydrogen-bonding groups were present." Ex. 2014 ¶ 54.

F. Analysis

Written description support may be found where the specification identifies either a representative number of species falling within the scope of the genus or structural features common to the members of the genus. *Ariad*, 598 F.3d at 1350. In this case, the challenged claims recite certain co-crystals, supramolecular synthons,[4] formed between at least one API and at least one co-crystal former (co-former). Ex. 1001, 25:18–23 (claim 10); Pet. 9. Claim 10 requires the at least one API to have a carboxamide, a carbonyl, or an amine first chemical functionality. *Id.* The claims do not

[4] The term "supramolecular synthon" refers to "[t]he sum of the components of a multiple-component non-covalent interaction, wherein the non-covalent interaction contributes to the formation of a discrete supramolecular entity or polymeric structure, wherein each component is a chemical functionality." Pet. 10.

limit the structure of co-former or the resulting co-crystal. Additionally, the specification of the '956 application states that the co-formers can be "solvent molecules, other drug molecules, GRAS compounds, or approved food additives." Ex. 1015 ¶ 9; *see also id.* at ¶ 42 ("The identified co-crystal formers can be, for example, a different API, a GRAS compound, a food additive, a low toxicity organic, or a metal-organic complex."). The '956 application discloses that GRAS compounds are compounds "Generally Regarded as Safe by the [Food and Drug Administration (FDA)]," and is preferably a non-pharmaceutical entity. *Id.* at ¶ 51. Thus, taken together, the '956 application discloses that the co-former recited in the challenged claims may be one of a solvent molecule, a pharmaceutical entity, a non-pharmaceutical entity, a food additive, a low toxicity organic, or a metal-organic complex.

Having considered the parties' positions and evidence of record, summarized above, we find that the parent '956 application fails to disclose a representative number of species "so that one of skill in the art can 'visualize or recognize' the members of the genus" recited in the challenged claims. *Ariad*, 598 F.3d at 1350. The specification discloses ten Examples, consisting of three unique APIs and ten unique co-formers, which we find to not adequately representative of all APIs and co-formers that provide co-crystals encompassed by the challenged claims. Ex. 1015 ¶ 56–177; Pet. 13–15. Here, we credit Dr. Roger's undisputed testimony that there are "thousands of known drug molecules," "well over one hundred GRAS compounds," and thus, "[v]ery conservatively, thousands of molecules would have qualified as a co-former as the term is used in the '344 patent's challenged claims." Ex. 1002 ¶ 72–73.

We also agree with Petitioner's assertion that "there are no structural

features common to all embodiments of the challenged claims" as the structure of the co-former is not limited or structurally defined by the specification. Pet. 13. Here, we credit the testimony of Dr. Roger stating that the claims recite functional limitations, highlighting the fact that the choice of co-former is based on whether the API and co-former are capable of forming a co-crystal through non-covalent hydrogen bonding (supramolecular synthons), rather than common structural feature among specific co-formers. Ex. 1002 ¶¶ 69, 75, 89–100; Ex. 1072 ¶¶ 74–77.

For a functionally-defined genus, "the written description requirement [can be met] when the art has established a correlation between structure and function." *Ariad*, 598 F.3d at 1350. Here, the challenge claims recite two types of functional limitations. First, independent claim 10 requires the co-former to have a second chemical functionality, which is defined as being complementary to the first chemical functionality via non-covalent hydrogen bonding. That is, the co-former's second chemical functionality must be complementary to either a carboxamide, carbonyl, or amine functionality of an API via non-covalent hydrogen bonding. Second, the non-covalent hydrogen bonding between the first chemical functionality of the API and the second chemical functionality of the co-former must result in the formation of supramolecular synthons.

As Dr. Rogers explains, the specification fails to provide any correlation between the structure of a disclosed co-former or its "second chemical functionality" and the function required by the claims, i.e., forming co-crystals that contain supramolecular synthons between an API and co-former via hydrogen bonding. Ex. 1002 ¶¶ 77–78, 80–82. The specification provides examples that show that supramolecular synthons can be formed with certain combinations of APIs ((carbamazepine, acetaminophen, and

phenytoin)) and co-formers (bipyridine (Example 1), 4,4'-bipyridine (Examples 3-5), p-phthalaldehyde (Example 7), nicotinamide (Example 8), saccharin (Example 9), 2,6-pyridinedicarboxylic acid (Example 10), 5-nitroisophthalic acid (Example 11), and adamantanetetracarboxylic acid (Example 13)). Ex. 1001, 11:60–24:2; Ex. 1002 ¶ 77. However, the specification lacks any teaching of a correlation between the structure of any given co-former and its ability to form a supramolecular synthon with an API as encompassed by the challenged claims.

Patent Owner does not dispute that the specification fails to disclose a correlation between structure and function. Rather, Patent Owner contends that "well-known principles of hydrogen bonding . . . would allow a POSITA to predict whether a co-crystal of an API satisfying [the challenged claims] would form." PO Resp. 17. Patent Owner explains that

> the POSITA would have: (1) an understanding of the likelihood of certain functional groups forming supramolecular synthons; (2) an understanding of a ranking of certain functional groups to form supramolecular synthons in the event multiple hydrogen bonding groups were present; and (3) sufficient working knowledge of whether hydrogen bonds between the API and some collection of co-formers were likely and, in the event of multiple potential synthons, the POSITA would have had a working knowledge of which ones would be preferred, even though other factors could impact synthon formation.

Sur-Reply 10 (citing Ex. 2014 ¶¶ 54–55). Patent Owner also directs our attention to Figure 24 of the '344 Patent (*see* Sec. I.B., *supra*.) that is provided "to assist in the selection of an API and co-former based on their chemical functionalities." PO Resp. 16. Thus, according to Patent Owner, in view of the "POSITA's extensive knowledge of hydrogen bonding and pharmaceutical formulation," the express disclosure of which APIs and co-formers were likely to form a co-crystal is not required to satisfy the written

description requirement. Sur-Reply 8–10.

Patent Owner supports its contentions with the testimony of Dr. Ward. Ex. 2014. Dr. Ward testifies that

> the well-known principles of hydrogen bonding, including those set forth by Dr. Etter, would allow a POSA to postulate whether a co-crystal of an API satisfying claims 10, 11, and/or 18 would likely form, regardless of whether a particular polymorph of a co-crystal forms or not. Specifically, in 2002/2003 a POSA would have understood the likelihood of certain functional groups (e.g., carboxylic acids, amines, nitro, amides, pyridines, alcohols) to form supramolecular synthons and crystal packing motifs defined by those synthons, based on numerous examples in single-component crystals and literature descriptions of hydrogen-bonding patterns ....

Ex. 2014 ¶ 54; *see also id.* at ¶¶ 38–43 (Dr. Ward summarizing the work of Dr. Etter and her hydrogen bonding rules ("Dr. Etter's rules")). Dr. Ward further testifies that "a POSA would have a good working knowledge of likely hydrogen-bonding interactions between a carboxamide and other hydrogen-bonding groups of co-formers, particularly because of the hydrogen-bonding motifs and 'rules' studied for more than a decade prior to 2002/2003." *Id.* at ¶ 55.

We have considered Patent Owner's arguments and evidence, but are not persuaded. Rather, we determine that the specification fails to describe the requisite structure-function correlation sufficient to provide written description support for the claimed invention, and further that basic knowledge of hydrogen bonding principles combined with high-throughput screening methodology is insufficient to establish or replace a structure-function correlation for the purposes of assessing written description support. As stated by Dr. Rogers,

> high-throughput screening is a methodology—without performing the experiments, it would not have provided a POSA with any guidance as to which co-crystallization methods, conditions, and variables to use for a given API and co-former combination, much less a specific stoichiometric ratio of API to co-former, nor how to optimize them or reduce the number of experiments required to prepare co-crystals within the full scope of the challenged claims. In designing a high-throughput screen, a POSA would need to identify the methods, conditions and variables to use.

Ex. 1072 ¶ 50.

We recognize that a POSA's perspective is key to the written description inquiry and many factors may inform the adequacy of a specification's disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." *Capon*, 418 F.3d at 1359. Under the circumstances presented here, however, we determine that the basic knowledge of hydrogen bonding principles or high-throughput screening methodology is insufficient to overcome the lack of predictability in co-crystal synthon formation. Here, we credit the testimony of both Dr. Ward and Dr. Rodgers that high-throughput screening methodologies (generally, not even specific to co-crystals) was just emerging and its potential had just begun to be realized. Ex. 2014 ¶ 49 (citing Ex. 2011, 275, 279); Ex. 1072 ¶ 45 (citing Ex. 2011, 285). We further credit the testimony of Dr. Rogers that

> neither Dr. Ward nor Patent Owners provide any evidence that high-throughput screening had been used by *anyone* as of March 2003 to evaluate or optimize co-crystallization conditions to prepare novel co-crystals, let alone those within the scope of the challenged claims. Nor does either provide any evidence of how a POSA would do so, or that high-throughput screening for this purpose was within the POSA's capabilities or routinely used. In

> fact, Luu 2012 (Ex. 1077) explains that Remenar (Ex. 2008), which was published in June 2003 (i.e., after the March 2003 date of the '956 application), was the first example of the use of high-throughput screening to prepare co-crystals. Ex. 1077, Luu 2012 at 356 (referring to Remenar (June) 2003 (i.e., Exhibit 2008 cited by Patent Owners), which was not prior art as of March 2003).

Ex. 1072 ¶ 43.

Regarding Etter's rules, we are persuaded by Dr. Rogers's testimony that "the lack of any disclosure in the '956 application about hydrogen bonding principles or Etter's 'rules' and importantly, how to apply them to identify co-crystals falling within the full scope of the challenged claims, demonstrates that there is insufficient support for written description of the full breadth of claimed co-crystals." *Id.* at ¶ 87. Importantly, Patent Owner failed to direct us to any persuasive evidence demonstrating that a POSA used or could have used the principles of Etter's rules to predict the full scope of co-crystals encompassed by the challenged claims. *Id.* at ¶ 60.

We recognize that Dr. Ward has testified to the contrary, including Dr. Ward's statement that "the examples in the '344 patent specification illustrate principles like those described for single component crystals with respect to synthon formation." Ex. 2014 ¶¶ 54–57. We are not persuaded, however, for the reasons discussed above, that the few examples disclosed in the '344 patent provide "either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus." *Ariad*, 598 F.3d at 1350. Nor are we persuaded that examples are sufficient to "establish[] a correlation between structure and function" for a co-former and its ability to form a supramolecular synthon with every API having a carboxamide encompassed by the challenged

claims. *Amgen*, 872 F.3d at 1378. Rather, considering the record as a whole, we determine that the '344 patent specification provides nothing more than "a research plan, leaving it to others to explore the unknown contours of the claimed genus." *AbbVie*, 759 F.3d at 1300.

We therefore find that the parent '956 application lacks written description support for the challenged claims, and thus, on the record before us, we determine that the effective filing date of the challenged claims is February 13, 2014, the filing date the '344 patent. Thus, the references relied upon by Petitioner (Hickey, Almarsson, and Martindale) qualify as prior art to the '344 patent. Pet. 33, 45.

III. ANALYSIS

A. Principles of Law

To anticipate a claim under 35 U.S.C. § 102, "a single prior art reference must expressly or inherently disclose each claim limitation." *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008). Accordingly, "'the dispositive question regarding anticipation [i]s whether one skilled in the art would reasonably understand or infer from the [prior art reference's] teaching' that every claim element was disclosed in that single reference." *Dayco Prods., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1368 (Fed. Cir. 2003) (quoting *In re Baxter Travenol Labs.*, 952 F.2d 388, 390 (Fed. Cir. 1991)).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which that subject matter pertains. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406

(2007). The question of obviousness is resolved based on underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective evidence of nonobviousness, if present. *Graham v. John Deere Co*., 383 U.S. 1, 17–18 (1966).

We analyze the asserted grounds of unpatentability in accordance with these principles.

B. Ground 1: Anticipation of Claims 10, 11, and 18 by Hickey

Petitioner asserts that Hickey anticipates claims 10, 11, and 18. Pet. 33–45. To support its contentions, Petitioner directs our attention to the disclosure of Hickey and provides a detailed claim analysis addressing how Hickey discloses each element of claims 10, 11, and 18. *Id.* (citing Ex. 1002). Petitioner contends that Hickey qualifies as prior art to the '344 patent "[b]ecause the challenged claims are not entitled to a 2002/2003 priority date." *Id.* at 33.

Patent Owner does not substantively address Petitioner's unpatentability contentions. *See generally* PO Resp.

Having considered the arguments and evidence presented at trial, we determine Petitioner has shown by a preponderance of the evidence that claims 10, 11, and 18 are anticipated by Hickey. Our summary follows. We start with an overview of the asserted prior art, Hickey.

1. Hickey (Ex. 1004)

Hickey discloses the use of carbamazepine as a co-crystal "that is suitable for drug development." Ex. 1004, 118. Hickey notes that "[c]arbamazepine . . . , an important anti-epileptic agent that has been in use for over 30 years, is an example of a water-insoluble drug that has a high

dose requirement (>100 mg/day) for therapeutic effect." Ex. 1004, 112. Hickey details a co-crystal of carbamazepine and saccharin, including "a performance comparison of the co-crystal to the marketed form of carbamazepine (Tegretol®, containing carbamazepine form 3)." Ex. 1004, 113. Hickey concludes that "[t]he present study illustrates the utility of a co-crystal as a type of material that is suitable for drug development." Ex. 1004, 118. Particularly, Hickey notes that "[t]he benefits of using the carbamazepine: saccharin co-crystal include (i) relative lack of polymorphism and equivalent chemical stability to the anhydrous polymorph, (ii) favorable dissolution properties and suspension stability, and (iii) comparable oral absorption profile in dogs compared with the commercial immediate release product." *Id.*

2. *Claim 10 and 18*

a) *[10a] A pharmaceutical composition comprising a pharmaceutically acceptable carrier and a therapeutically effective amount of [a co-crystal]*

Petitioner asserts that Hickey discloses a "pharmaceutically acceptable carrier" by describing the preparation of alpha-lactose monohydrate (lactose) into a capsule. Pet. 42 (citing Ex. 1004, 115, 118; Ex. 1002 ¶¶ 186–88). Petitioner further argues that the described composition would have been understood also to include a co-crystal as Hickey discloses the capsule to contain "'200 mg of carbamazepine,' i.e., the same amount of carbamazepine included in the commercial Tegretol® product." Pet. 42–43 (citing Ex. 1004, 112, 115, 118; Ex. 1002 ¶¶ 187–88; Ex. 1003 ¶¶ 58–59). Petitioner asserts that the capsules were reported to be a "'viable alternative' to Tegretol®" and thus, a person of ordinary skill in the art would have concluded "that the Hickey capsules included an amount

of co-crystal that was therapeutically effective as an anti-epileptic." Pet. 43 (citing Ex. 1004, 112–13, 115, 118; Ex. 1002 ¶¶ 186–89; Ex. 1003 ¶¶ 57, 59–60).

Patent Owner does not dispute that Hickey discloses the preamble of claim 10. *See generally* PO Resp. We are persuaded that Hickey does.

> b) *[10b] a co-crystal comprising supramolecular synthons, each supramolecular synthon formed from stoichiometric amounts of at least one active pharmaceutical ingredient (API) and at least one co-former*

Petitioner notes that "Hickey discloses a 1:1 co-crystal of carbamazepine and saccharin." Pet. 35 (citing Ex. 1004, 113–15. Petitioner argues that Hickey's description of carbamazepine meets the "agreed-upon API definition." Pet. 36 (citing Ex. 1004, 112) (emphasis omitted). Further, Petitioner argues that "[a] POSA would understand that saccharin is a co-former in the co-crystal because it is complementary to, and forms a co-crystal with, carbamazepine." *Id.* (citing Ex. 1004, 113–15) (emphasis omitted). Therefore, Petitioner asserts that "[t]he carbamazepine/saccharin co-crystal qualifies as a co-crystal under the '344 patent." Pet. 37.

Patent Owner does not dispute that the prior art teaches limitation [10b]. *See generally* PO Resp.

Having considered the parties' positions and evidence of record, summarized above, we are persuaded that Hickey teaches limitation [10b].

c) *[10c] Wherein the API has a first chemical functionality that permits formation of API homosynthons through non-covalent hydrogen bonding when the API is in its pure form*

[10g] wherein the first chemical functionality is (i) a carboxamide, (ii) a carbonyl, or (iii) an amine

[18] wherein the first chemical functionality is a carboxamide

Petitioner asserts Hickey discloses these claim limitations by describing carbamazepine. Pet. 40 (citing Ex. 1002 ¶ 173). Petitioner argues that carbamazepine discloses limitation [10c] because "[t]he carboxamide on one carbamazepine hydrogen bonds with the carboxamide of an adjacent carbamazepine to form an API homosynthon, *i.e.*, a synthon between identical and complementary chemical functionalities (the carboxamide groups) of the API (carbamazepine)." Pet. 39 (citing Ex. 1005, figure 50A, 6:38–40, 6:47–61; Ex. 1002 ¶¶ 171–73).

Patent Owner does not dispute that the prior art teaches the limitations of [10c], [10g], or claim 18. *See generally* PO Resp.

Having considered the parties' positions and evidence of record, summarized above, we are persuaded that Hickey teaches the limitations of [10c], [10g], and claim 18.

d) *[10d] wherein the co-former has a second chemical functionality compl[e]mentary to the first chemical functionality via non-covalent hydrogen bonding*

[10f] wherein the supramolecular synthons are formed via non-covalent hydrogen bonding between the first chemical functionality of the API and the second chemical functionality of the co-former

Petitioner argues that "saccharin has a second chemical functionality . . . that forms non-covalent hydrogen bonds with the first chemical

functionality (carboxamide) of the API (carbamazepine)." Pet. 40–41 (citing Ex. 1004, 113; Ex. 1002 ¶¶ 166–67, 174–75,180–81). Further, Petitioner notes the "same non-covalent hydrogen bonding between the first chemical functionality of the API and the second chemical functionality of the co-former gives rise to supramolecular synthons." Pet. 41 (citing Ex. 1002 ¶¶ 166–67, 180–82).

Patent Owner does not dispute that the prior art teaches limitations [10d] or [10f]. *See generally* PO Resp.

Having considered the parties' positions and evidence of record, summarized above, we are persuaded that Hickey teaches limitations [10d] and [10f].

e) [10e] wherein said co-former is a solid at room temperature and atmospheric pressure when the co-former is in its pure form

Petitioner asserts the co-former disclosed in Hickey, saccharin, meets the claim limitation. Petitioner notes that saccharin "has a melting point of 228.8 °C" and thus, "saccharin is a solid at room temperature and atmospheric pressure when in its pure form." Pet. 41–42.

Patent Owner does not dispute that the prior art teaches limitation [10e]. *See generally* PO Resp.

Having considered the parties' positions and evidence of record, summarized above, we are persuaded that Hickey teaches limitation [10e].

3. Claim 11

Claim 11 incorporates all limitations of claim 10 and additionally requires that the supramolecular synthon "comprises a heterosynthon dimer formed by noncovalent hydrogen bonding of the API to the co-former."

Ex. 1001, 25:40–43. Hickey discloses a co-crystal comprising an API (carbamazepine) and a co-former (saccharin). Ex. 1004, 113–15. Petitioner contends that non-covalent hydrogen bonding exists between the carboxamide group of carbamazepine and saccharin. Pet. 44 (citing Ex. 1004, 113–15). Petitioner contends that this interaction forms a heterosynthon because the "first chemical functionality (carboxamide) of the API and the second chemical functionality of the co-former are different chemical functionalities." *Id.* (citing Ex. 1002 ¶¶ 196–98) (emphasis omitted). Here, we credit the testimony of Dr. Rodgers that

> The carboxamide on carbamazepine interacts with the second chemical functionality on saccharin via non-covalent hydrogen bonding (indicated by the dashed line shaded red). The first chemical functionality of the API carbamazepine and the second chemical functionality of the co-former saccharin are different chemical functionalities and, thus, the carbamazepine and saccharin co-crystal comprises a heterosynthon dimer as the Parties have agreed to define it (*i.e.*, a synthon formed by two different, yet complementary chemical functionalities.

Ex. 1002 ¶ 196.

Patent Owner does not dispute that the prior art teaches the limitation of claim 11. *See generally* PO Resp.

Having considered the parties' positions and evidence of record, summarized above, we are persuaded that Hickey teaches the limitation of claim 11.

4. Conclusion

As summarized above, it is undisputed that Hickey discloses each limitation of the challenged claims. Having considered the parties positions and evidence of record, we determine that Petitioner has shown by a

preponderance of evidence that claims 10, 11, and 18 are anticipated by Hickey.

C. Grounds 2 and 3: Anticipation or Obviousness of Claims 10, 11, and 18 based on Almarsson

Petitioner asserts that claims 10, 11, and 18 are anticipated by Almarsson. Pet. 48–62. To support its contentions, Petitioner directs our attention to the disclosure of Almarsson and provides a detailed claim analysis addressing how Almarsson discloses each element of claims 10, 11, and 18. *Id.* (citing Ex. 1002). Petitioner also asserts, in the alternative, that claims 10, 11, and 18 would have been obvious over Almarsson. *Id.* Petitioner also asserts, in the alternative, that claims 10, 11, and 18 would have been obvious over the combination of Almarsson, Hickey, and Martindale. *Id.* at 56–62.

Patent Owner does not substantively address Petitioner's unpatentability contentions. *See generally*, PO Resp.

We have discussed Petitioner's Ground 1 above, and concluded that claims 10, 11, and 18 are each unpatentable as anticipated by Hickey. Therefore, we do not address in detail or reach any conclusion on patentability for Petitioner's Grounds 2 and 3 based on Almarsson.

IV. CONCLUSION

We conclude, based on a preponderance of the evidence, that claims 10, 11, and 18 are unpatentable. In summary:

Claim(s)	35 U.S.C. §	Reference(s)/Basis	Claim(s) Shown Unpatentable	Claim(s) Not Shown Unpatentable
10, 11, 18	102	Hickey	10, 11, 18	
10, 11, 18	102/103	Almarsson		
10, 11, 18	103	Almarsson, Hickey, Martindale		
Overall Outcome			10, 11, 18	

V. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that claims 10, 11, and 18 of U.S. Patent No. 10,633,344 B2 are proven unpatentable;

FURTHER ORDERED that, because this Decision is final, a party to the proceeding seeking judicial review of the Decision must comply with the notice and service requirements of 37 C.F.R. § 90.2.

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